

Proposed Agenda

Meeting with Oxitec, Ltd.

March 7, 2017

Introductions and any statements from Rick, Ritu, Bob, and Mike

Update from Oxitec re: what their current plans are and what they hope to gain from the meeting.

Brief comments on Section 18 process – Dan Rosenblatt, RD

Description of EUP – Process – Elizabeth M.

PRIA Code B620

Actual studies should be formatted per PR Notice 2011-3.

Share information with BPPD at the same time as submitting to front end process.

Notice of Receipt - 30 day comment period.

Technical screen.

Description of EUP - Information/data to support an EUP application or developed via an EUP – Chris W.

Efficacy and need for detailed description of testing protocol in Section G – Wiebke T.

Human Health – John K.

Eco – Shannon B.

Status Update FDA - Ritu

Conclusions